

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR
ADEQUATE DIRECTIONS OR WARNING STATEMENTS***

6314. Ring's Golden Herb Tonic. (F.D.C. No. 44431. S. No. 21-662 R.)

QUANTITY: 8 bulk cans of Special Soft Extract Formula L-199, and 54 cases, each containing 12 16-oz. btl., and 124 cases, each containing 36 8-oz. btl., of *Ring's Golden Herb Tonic*, at Grand Rapids, Mich., in possession of Dewey Products Co.

SHIPPED: Prior to 3-10-60, from Lyndhurst, N.J.

LABEL IN PART: (Can) "52½ Pounds Special Soft Extract Formula L-199 Containing the following: Blue Flag Root Black Cohosh Root Boneset Herb Burdock Root Yellow Dock Root Juniper Berries Mandrake Root Queen of Meadow Root Gentian Root Colombo Root Blue Cohosh Root Quassia Chips Dandelion Root Med T V Senna Leaves Sodium Benzoate"; and (repacked btl.) "Rings Golden Herb Tonic Lab Control No. 7330 An All Herb Compound Alternative. Diuretic. Nervine. Stomatic. Especially compounded from * * * Directions * * * Ring Laboratories, Inc. Grand Rapids, Mich."

ACCOMPANYING LABELING: Brochures entitled "Enjoy the Sunshine of Good Health" and a number of loose bottle labels.

RESULTS OF INVESTIGATION: The article in the bottles was manufactured by Dewey Products Co., for Ring Laboratories, Inc., from the article in the bulk cans, shipped as described above, by mixing with water and sodium benzoate. The article, after manufacture, was packed into bottles labeled as described above.

LIBELED: 4-18-60, W. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis; rheumatism; neuritis; stiff joints; sciatica; kidney-bladder disorders; backache; high blood pressure; anemia; stomach and liver ailments; constipation; indigestion; gas; rundown condition; loss of appetite and energy; gall infection; hemorrhoids; and many other systemic disturbances; and that the article was an alterative, a diuretic, a nervine and a stomatic; and 502(f) (2)—certain ingredients of the article would exert a laxative effect and its labeling failed to bear a statement warning that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present; or that frequent or continued use may result in dependence on laxatives.

DISPOSITION: 8-1-60. Consent—claimed by Ring Laboratories, Inc., and relabeled.

6315. Succin-Salimide tablets, Ar-Thry-Go tablets and Ar-Thry-Go ointment.
(F.D.C. No. 44406. S. Nos. 56-713/4 P.)

QUANTITY: 19,168 *Succin-Salimide tablets*, 24 60-tablet btl., 24 120-tablet btl., and 6 252-tablet btl., of *Ar-Thry-Go tablets*, and 16 ctns., each containing 12 30-oz. jars of *Ar-Thry-Go ointment*, at Atlanta, Ga., in possession of Hussey Distributing Co.

SHIPPED: 12-21-59 and 1-22-60, from Philadelphia, Pa., (tablets) by Richlyn Laboratories and (ointment) by Windsor Chemical Laboratories.

*See also Nos. 6301, 6302, 6312.

LABEL IN PART: (Drum) "25,000 Tablets SUCCIN-SALIMIDE Each tablet Contains: Calcium Succinate 3 gr., Salicylamide 3 gr., Thiamine HCl. 1 mg., Ascorbic Acid 20 mg. Used for the relief of symptoms of Arthritis, Rheumatism, Sciatica, Neuritis, Bursitis, and Lumbago * * * Dosage * * * 11307 Richlyn Laboratories, Philadelphia, Pa."; (btl.) "AR-THRY-GO Tablets Each Tablet Contains Calcium Succinate 3 gr., Salicylamide 3 gr., Thiamine HCl. 1 mg. Ascorbic Acid 20 mg. Used for the relief of symptoms of Arthritis, Rheumatism, Sciatica, Neuritis, Bursitis, and Lumbago. Dosage * * * A Husco Product Distributed by Hussey Dist. Co. Atlanta, Georgia"; and (jar) "Ar-Thry-Go Ointment for Relief of Pains and Aches * * * Active Ingredients Methyl Salicylate, Menthol and Camphor. A Husco Product Distributed by Hussey Dist. Co. Atlanta, Ga. Directions."

ACCOMPANYING LABELING: Leaflets entitled "Why Suffer Needlessly."

RESULTS OF INVESTIGATION: The leaflets were printed locally for the dealer and the *Ar-Thry-Go tablets* consisted of *Succin-Salimide tablets* which had been repacked and relabeled by the dealer after shipment as described above.

LIBELED: 3-28-60, N. Dist. Ga.

CHARGE: *Succin-Salimide tablets* and *Ar-Thry-Go tablets*, 502(a)—when shipped and while held for sale, the labeling of the tablets contained false and misleading representations that the tablets were an adequate and effective treatment for arthritis, rheumatism, sciatica, neuritis, bursitis, and lumbago; and 502(f) (2)—the tablets contained salicylamide, and their labeling failed to bear such adequate warnings against use in those pathological conditions or by children where their use may be dangerous to health or against unsafe dosage or methods or duration of application in such manner and form as are necessary for the protection of users.

Ar-Thry-Go ointment, 502(a)—the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, neuritis, sciatica, bursitis, inflammation and congestion due to common colds and "flu."

DISPOSITION: 7-21-60. Default—destruction.

6316. Supplement to notice of judgment on drugs and devices No. 4654. Hoxsey treatment for internal cancer. (Inj. No. 232.) *See also* N.J. No. 6317 in this supplement.

On 9-16-60, the United States District Court for the Northern District of Texas entered a supplemental consent decree of permanent injunction against Harry M. Hoxsey as follows:

ESTES, *District Judge*: "On October 26, 1953, this Court, pursuant to the mandate of the United States Court of Appeals for the Fifth Circuit, entered a decree of permanent injunction against Hoxsey Cancer Clinic, a partnership, and Harry M. Hoxsey, an individual, which said permanent decree of injunction remains in full force and effect.

"Thereafter, on May 1, 1957, the Clinic was leased to Harry R. Taylor, D.O., under a lease which provided for rental to be determined by the net profits from the operations of said Clinic, which said arrangement authorized Harry R. Taylor to use the Hoxsey treatment and the patient files and records accumulated by the Hoxsey Cancer Clinic and Harry M. Hoxsey.

"Harry R. Taylor having this day signed a consent decree enjoining and restraining him from further distribution of the Hoxsey treatment, and all similar drugs represented to be effective in the treatment of cancer in man;

"IT IS, pursuant to the consent of said Harry M. Hoxsey, ORDERED that the said Harry M. Hoxsey, his agents, servants, employees, representa-

tives and assigns, and all persons in active concert or participation with him, be further perpetually enjoined

- (a) from participating, directly or indirectly, in the profits of the said Clinic through the lease contract with Harry R. Taylor after December 31, 1960, which said lease contract shall terminate on or before December 31, 1960, when said premises are vacated by Dr. Harry R. Taylor;
- (b) from the further operation of the Clinic at 4507 Gaston Avenue, or elsewhere, as the Hoxsey Cancer Clinic, Hoxsey Clinic, Taylor Clinic, and as any successor to any such Clinic.

"AND IT IS FURTHER ORDERED that the Clinic building and its equipment may be leased for legitimate medical or osteopathic practice, but only if it does not involve directly or indirectly in any way whatsoever the use of the Hoxsey treatment, being the drugs described in the Decree of October 26, 1953, or any similar drugs, and does not involve the lease or use of the patient records which have been built up through the operation of the Hoxsey Cancer Clinic, the Hoxsey Clinic, the Taylor Clinic, and Harry M. Hoxsey and his physician employees.

"AND IT IS FURTHER ORDERED that there be a complete and final discontinuation of the Hoxsey treatment, and that the said Harry M. Hoxsey shall so notify any person communicating with him about the said treatment."

6317. Hoxsey treatment for internal cancer. (Inj. No. 382). See also N.J. No. 6316 in this supplement.

COMPLAINT FOR INJUNCTION FILED: 9-16-60, N. Dist. Tex., against Harry R. Taylor, t/a Taylor Clinic, Dallas, Tex., and against Alan F. de Vore and Walter J. Williams, medical practitioners employed by Harry R. Taylor, to enjoin such parties against causing the *Hoxsey treatment for internal cancer* to be introduced and delivered for introduction into interstate commerce.

NATURE OF DRUGS: The complaint alleged that the essential part of the *Hoxsey treatment for internal cancer* was a liquid medicine, variously known as "Tonic Black" or "Liquid Tonic (Black)" or "Regular Tonic" or "Liquid Tonic," and labeled as "Concentrate Solution," and containing the following ingredients: Extract Cascara Sagrada, Potassium Iodide, Red Clover, Burdock Root, Alfalfa Leaf, Prickly Ash Bark, Water, Buckthorn Bark, Licorice, Stillingia Root, and Berberis Root; and that at times the essential part of the Hoxsey treatment had been compounded and dispensed in tablet form, known variously as "Calton Tablets," "Rx 100 Tablets" or "Hoxsey Tablets #100, S. C. Black," containing the following ingredients: Potassium Iodide, Licorice, Red Clover, Burdock Root, Stillingia Root, Berberis Root, Poke Root, Extract Cascara Sagrada Aromatic, U. S. P. XIV, Prickly Ash Bark, and Buckthorn Bark. It was also alleged that if a patient could not tolerate the "Liquid Tonic (Black)" another liquid medicine was substituted for it, and that such liquid medicine was labeled as "Concentrate Solution" and variously known as "Red Tonic" or "Lactate Red Solution" or "Lactate Liquid" or "Lactate (Red)," containing the following ingredients: Potassium Iodide, Red Clover, Burdock Root, Alfalfa Leaf, Prickly Ash Bark, Elixir Lactated Pepsin, Buckthorn Bark, Stillingia Root, and Berberis Root; and that at times such alternative form of the Hoxsey treatment had been compounded and dispensed in tablet form known variously as "Lactabs" or "Lactabs, S. C. Red" or "Lactate Tablets," containing the ingredients Potassium Iodide, Red Clover, Stillingia Root, Berberis Root, Poke Root, Buckthorn Bark, and Pepsin.

ACCOMPANYING LABELING: Leaflets entitled "Instructions for Melanomas, Hodgkins Disease, Leukemias, and Lympho-Sarcoma," "Instructions For Bone